



EUROPEAN COMMISSION ROADMAP TOWARDS PHASING OUT ANIMAL TESTING EFSA'S CONTRIBUTION

EFSA Stakeholder Bureau meeting,
17th October 2025

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Commission's response to the European citizens' initiative

SAVE CRUELTY-FREE COSMETICS - COMMIT TO A EUROPE WITHOUT ANIMAL TESTING

2021

July 2023
#EUTakeTheInitiative



ENGAGEMENT

1,217,916 signatories from 27 EU Member States.

WHY?

or How it started....

COMMISSION'S RESPONSE TO THE CITIZENS' INITIATIVE

The Commission is proposing the following actions in response to the objectives of the citizens' initiative:

- continue to **apply and enforce the animal testing ban** in the framework of the EU Cosmetics Regulation;
- consider the need for legislative changes to further **clarify the interface between the EU Cosmetics and REACH Regulations** based on the outcome of an ongoing judicial review;
- kick off work on a roadmap **towards replacing animal testing in chemical safety assessments**, with multiple actions and a step-by-step path to replacing animal testing, involving all relevant stakeholders;
- initiate a series of actions to accelerate the reduction of **animal testing in research, education and training**, including exploratory workshops, and sustaining new training initiatives for early career scientists;
- continue to support research on alternatives to animal testing with **EU funding**.

More info in: https://citizens-initiative.europa.eu/save-cruelty-free-cosmetics-commit-europe-without-animal-testing_en



The roadmap

Aims to provide a **plan/schedule** to accelerate reaching the goal of phasing out animal testing

Commission Communication (15 pages)

+ Staff working document

- Applicable to **all relevant pieces of EU chemical legislation** that might lead to animal testing for **chemical safety assessments**
 - 15 legislative areas identified
- To be published in Q1 of 2026

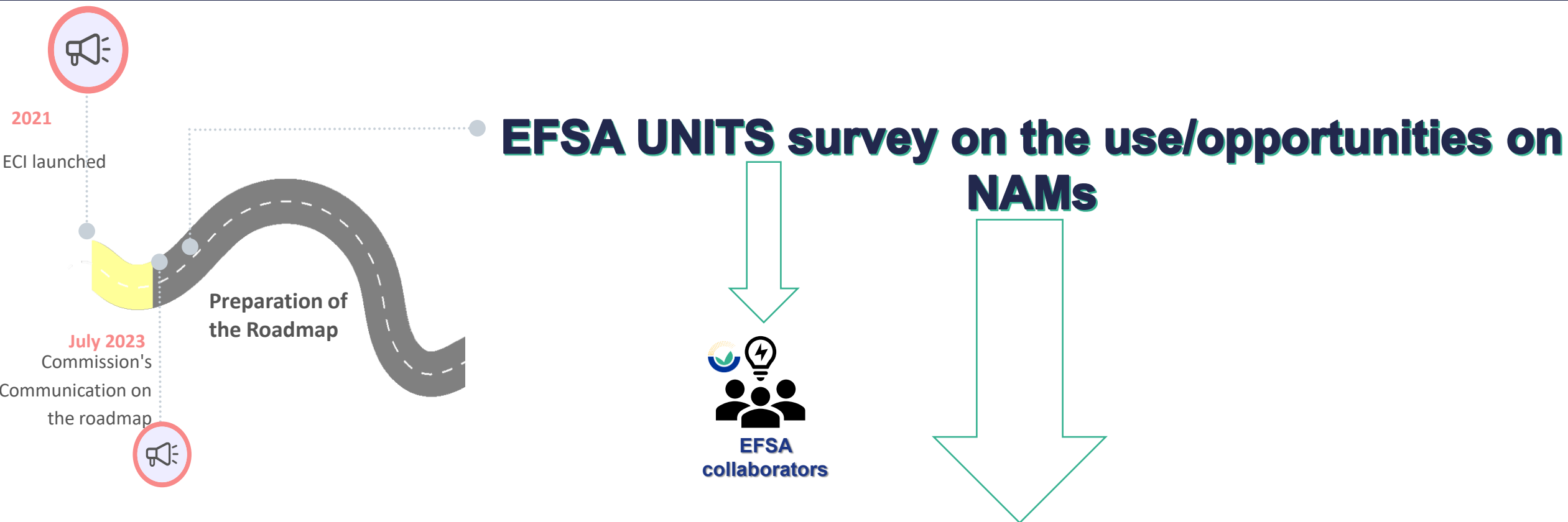
All info in:



Roadmap towards phasing out animal testing - European Commission



HOW IT STARTED AT EFSA



EFSA Roadmap input to HH and ERA:

1. Experimental animal-based methods currently in use under the different pieces of legislation or sectors applicable to EFSA, and the information they provide
2. Short-term available but not yet implemented replacement methods or approaches
3. Potential short-, medium- and long-term considerations to reduce or replace the need for animal testing

Disclaimers from EC

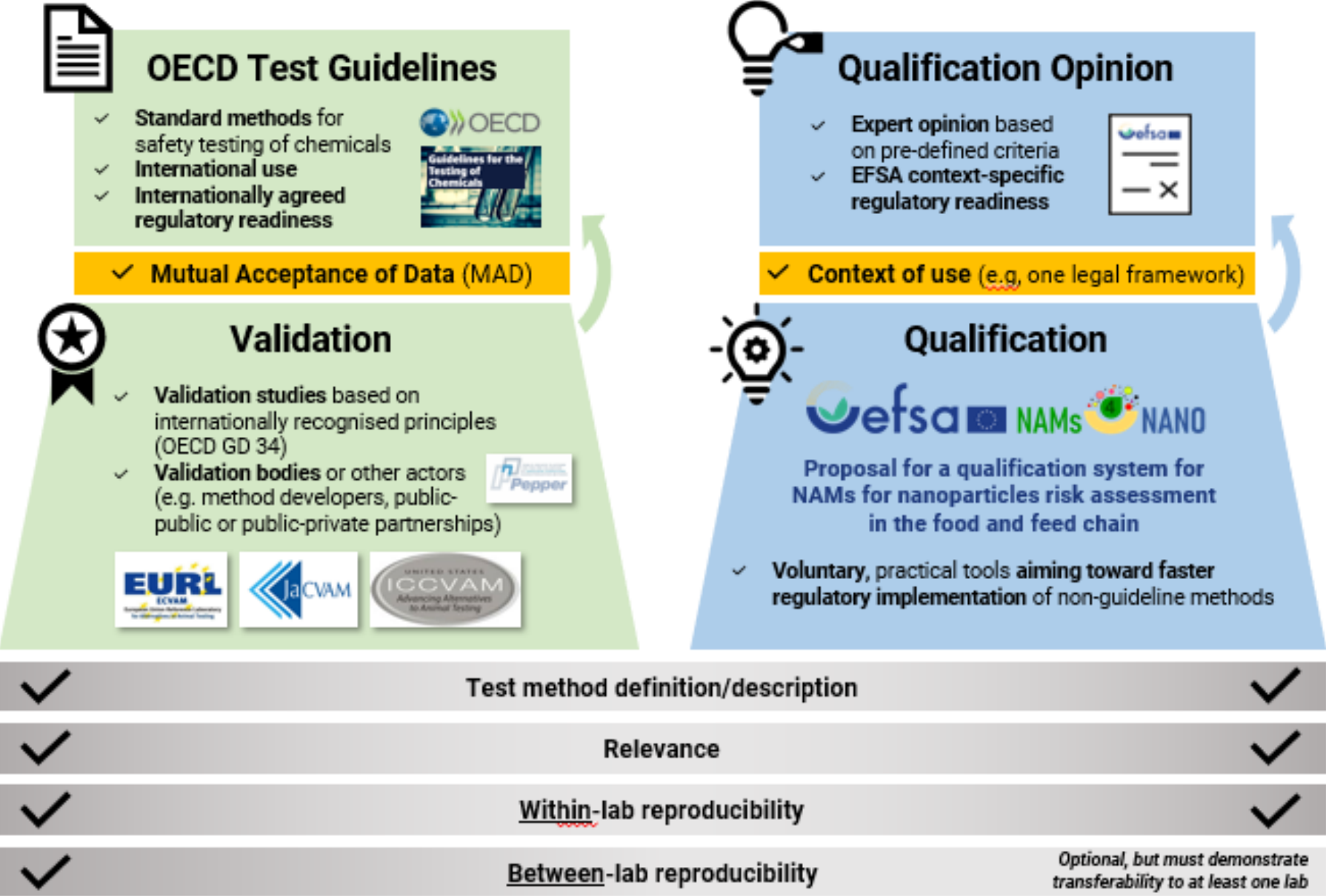
- The Roadmap (Commission Communication + Staff Working Document)
 - will contain recommendations (action points) on specific human health or ecotoxicological areas of concern or organisational structures
 - **does not pre-empt or indicate any changes in legislation**
- Phasing out animal testing will make it necessary to develop further animal-free methods or approaches. → will require discussions with experts and Member State representatives during the **implementation phase** of the Roadmap
- **Indicators** that help to monitor the progress of the implementation
- Recommended **organisational structures** that are necessary for the implementation process



Designed by frontiersing.org

The roadmap will 'outline the path to **expand and accelerate** the **development, validation** and **implementation of non-animal methods** ...'

Validation vs Qualification: EFSA example



Commission roadmap towards **phasing out animal testing** for chemical safety assessments.



Infographics by **EFSA**, the NAMs4NANO grant holders (BfR et al), OECD, and JRC.



NEW HUMAN HEALTH SAFETY ASSESSMENT PARADIGM

Commission roadmap
towards **phasing out**
animal testing for
chemical safety
assessments. 

THE ULTIMATE GOAL

- **Human-centric**, animal-free safety assessments
- **High level of protection**, demonstrated explicitly and transparently
- **Mechanistic** understanding to distinguish relevant from irrelevant substance effects
- **Up-to-date** science
- High-throughput, efficient
- Integrated with environmental safety

- The Roadmap goals and recommendations are **broad to support flexible** implementation across legal frameworks

Short-term

Medium-term

Long-term

1. Establish cross-sector, animal-free Next Generation Risk Assessment (NGRA) frameworks

Increase use of computational approaches

Standardise ADME, PBK modelling & IVIVE

Standardise PoD & tox signatures derivation from NAM data for complex regulatory endpoints

Development of NGRA workflow for enabling systemic use of NAMs

Establish NAM based frameworks for Carcinogenicity, DART, DNT, Endocrine Disruption, Genotoxicity & Systemic Toxicity

Nanomaterials / Nanoparticles Risk Assessment

RECOMMENDATIONS

Conduct uncertainty analysis & set acceptance criteria

Modernise CLP criteria

2. Reduce number of animals & species tested, where justified

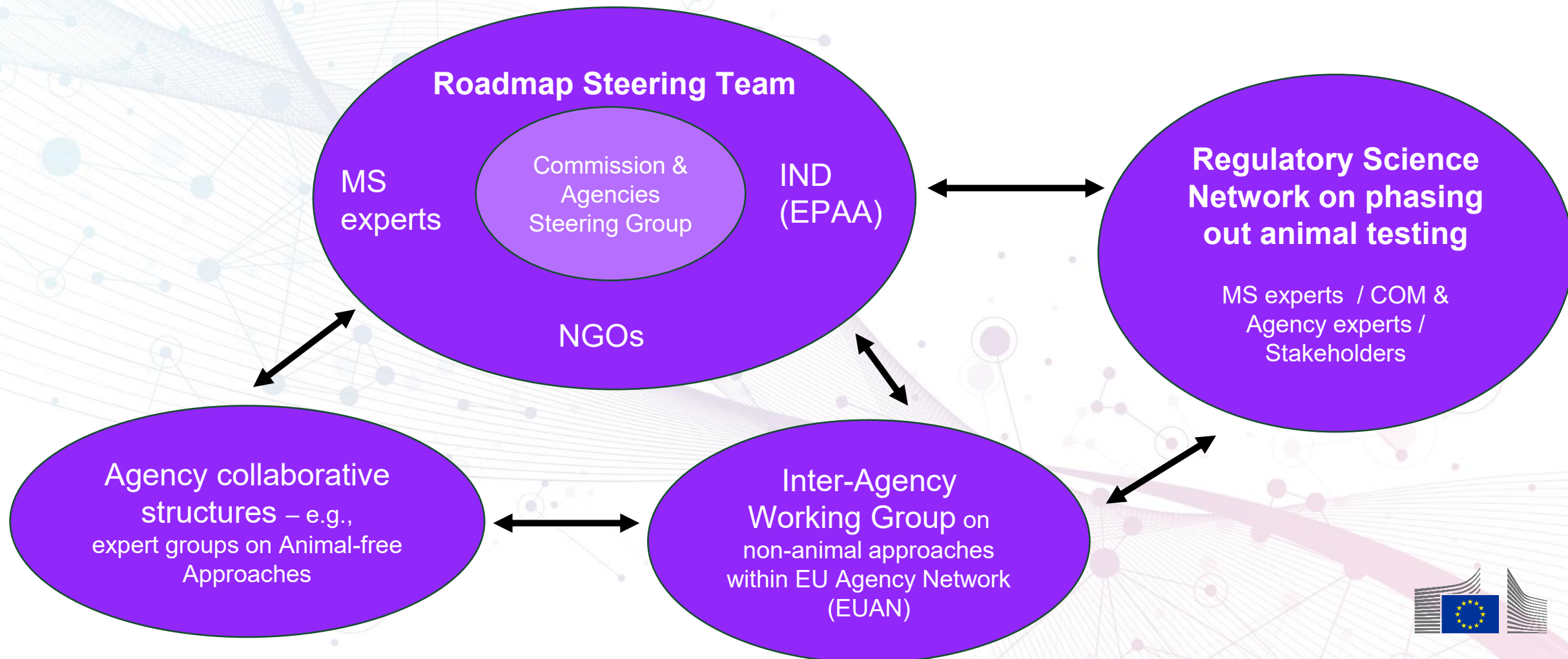
2nd species sub-chronic testing removal, 90-day dog study removal

Develop tiered approaches to minimise use of animals & maximise use of NAMs

Reduce long-term *in vivo* HH studies through **smart** *in vivo* studies

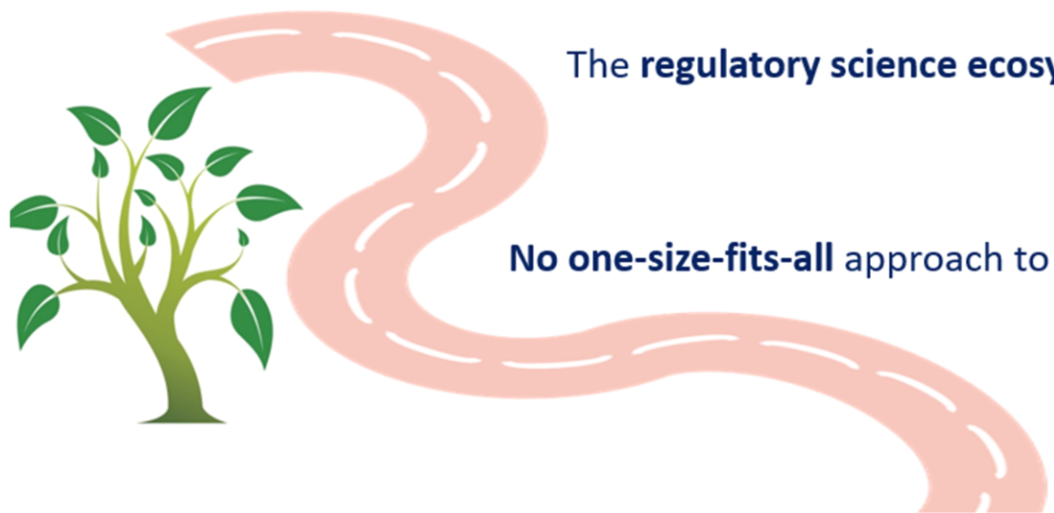
Implementation phase Organisational structures – draft proposal

Commission roadmap
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To finish

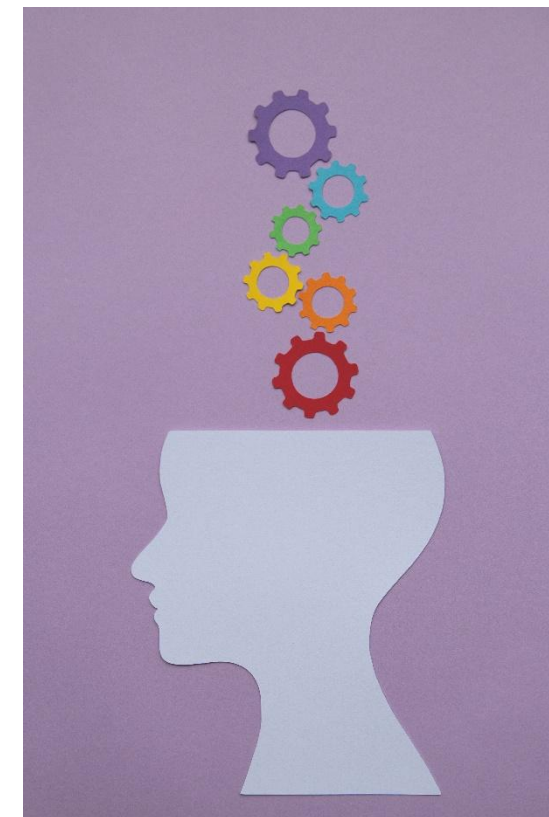
Stakeholder insights for the road ahead (1)



The **regulatory science ecosystem** is wide and very diverse

No one-size-fits-all approach to effect change will work

Need to **embrace the beauty of diversity among stakeholders** and respect different priorities and different ways of accomplishing the same goals



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